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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,300	08/10/2001	Craig A. Rosen	PA101	2089

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HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER	
SHEINBERG, MONIKA B	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/925,300	ROSEN ET AL.	
	Examiner	Art Unit	
	Monika B Sheinberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction/Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 9, 10, 14, and 21, drawn to polynucleotides and compositions containing same, classified in Class 536, subclass 23.1; Class 435, subclasses 243, 320.1, and 325; and Class 514, subclass 44. (If this group is elected, please see sequence election requirement further below).

II. Claim 8, drawn to a method of making a recombinant host cell, classified in Class 435, subclass 440. (If this group is elected, please see sequence election requirement further below).

III. Claims 11, 12, and 16, drawn to polypeptides, classified in Class 530, subclass 350 and 514. (If this group is elected, please see sequence election requirement further below).

IV. Claim 13, drawn to an antibody, classified in Class 530, subclass 387.1. (If this group is elected, please see sequence election requirement further below).

V. Claim 15, drawn to methods of expression of polypeptides, classified in Class 435, subclass 69.1. (If this group is elected, please see sequence election requirement further below).

VI. Claim 17, drawn to a method of preventing, treating, or ameliorating a medical condition, classified in class 514, subclass 44. (If this group is elected, please see sequence election requirement further below; *In addition*, if this group is elected then specie election requirement is also required wherein the species are Specie VIA: polypeptide and Specie VIB: a polynucleotide).

VII. Claim 18, drawn to a method of diagnosing a medical condition using polynucleotide mutation detection, classified in class 435, subclass 6. (If this group is elected, please see sequence election requirement further below).

VIII. Claim 19, drawn to a method for diagnosing a medical condition using polypeptide expression detection, classified in class 435, subclass 7.1. (If this group is elected, please see sequence election requirement further below).

IX. Claims 20 and 23, drawn to a method for identifying a binding partner to a polypeptide and said binding partner composition, classified in class classified in Class 436, subclass 501. (If this group is elected, please see sequence election requirement further below).

X. Claim 22, drawn to a method of identifying an activity of a protein in a cell, classified in class 435, subclass 7.1 and 69.1. (If this group is elected, please see sequence election requirement further below).

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups (I, II, V, VI [polynucleotide specie], and VII); Groups (III, VI [polypeptide specie], VIII, IX, and X); and Group IV are independent inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups III, VI [polypeptide specie], VIII, IX, and X the critical feature is a polypeptide; for Groups I, II, V, VI [polynucleotide specie], and VII the critical feature is nucleic acid; and for Group IV the critical feature is an antibody. It is acknowledged that various processing steps may cause a polypeptide of the above Groups to be directed as to its synthesis by a polynucleotide of the above Groups, however, the completely separate chemical types of the inventions of the nucleic acid, polypeptide, and antibody Groups supports the undue search burden if both were examined together. Additionally, polynucleotides, polypeptides, and antibodies have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the five Groupings of (I, II, V, VI [polynucleotide specie], and VII); (III, VI [polypeptide specie], VIII, IX, and X); and (IV) are independent and/or distinct invention types for restriction purposes.

The inventions of Group I and Groups II, V, VI [polynucleotide specie], and VII are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be

practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case the nucleic acids of Group I can be used in the distinct processes of the inventions of Groups II, V, VI [polynucleotide specie], and VII. One use is directed to polypeptide expression and the other to screening via nucleic acid binding reactions. Alternatively, the nucleic acids of Group I can be used in antisense therapy which is also a clearly distinct usage of such nucleic acids.

The inventions of Group III and Groups VI [polypeptide specie], VIII, IX, and X are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case the polypeptides of Group III can be used in the distinct processes of the inventions of Groups VI [polypeptide specie], VIII, IX, and X and in therapeutic processes to replace a missing protein, or, alternatively, the activity of a protein can be utilized in an industrial process for chemical processing. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Sequence Election Requirement Applicable to All Groups:

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicant(s) must further elect a single amino acid sequence (SEQ ID NO). For an elected Group drawn to nucleic acid sequences, the Applicant(s) must elect a single nucleic acid sequence (SEQ ID NO) (See MPEP 803.04). It is noted that this is a restriction requirement to a single sequence and NOT a specie election requirement.

MPEP 803.04 states:

"Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq."

It has been determined that 1(ONE) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of 1(one) sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims.

Examination will be restricted to only the elected sequence.

SPECIE Election Requirement Applicable to Group VI

This application contains claims directed to the following patentably distinct species of the claimed invention: Species VIA: polypeptide and Species VIB: polynucleotide.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 17 is generic to Species VIA and VIB.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 1 P.M to 8 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

February 20, 2003

Monika B. Sheinberg
Art Unit 1634
MBS

JEHANNE SOUAYA
PATENT EXAMINER
Jehanne Souaya
2/20/03